OneLab 1.16 Operational Qualification Procedure





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1. Operational Qualification (OQ)

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	Function	Name	Date	
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Reviewed by	Senior Software Manager	Adrien Pegaz-Blanc	26 September2022	

The **Operational Qualification (OQ)** is a test process that evaluates the proper functioning of a facility or an appliance. The Operational Qualification (OQ) may only be performed after a successfully completed Installation Qualification (IQ). The documentation for an Operational Qualification consists of:

- OQ test plan
- OQ report

1.1.0Q test plan

The **OQ** test plan contains detailed information of the tests to be performed on the respective equipment in the context of the Operation Qualification (OQ). This test plan contains detailed specifications on the course of the test itself.

After completion of the OQ test plan, the results are summarized, evaluated, and combined in an OQ report. All deviations, as well as measures taken to eliminate these, are documented. After the deviations have been eliminated, they must be tested again, documented, and evaluated in a new OQ report.

The Operational Qualification template for OneLab is reported in the next page.





1.2. Getting started

This Operational Qualification procedure is based on the execution of a set of workflows to test the correct functionality of different features of the system.

In case of an enterprise deployment, Installation Qualification must be successfully performed before starting the Operation Qualification procedure.

A) SaaS / Minor release OQ Process

In case of an OQ Process on the SaaS environment or being done for a minor release, only the <u>Workflow 3</u> could be executed.

In this case, requirements would be to log in with a user having one of the roles listed in the related requirements- this could be a user created in an earlier qualification workflow, one of your own configured users, or, when using an outside expert to run qualification, a user account / accounts configured specifically for this individual. All used users should be in the same lab.

B) Enterprise OQ Process

Onal ah LIBI

a. Requirements: about initial configuration

- The OQ performer must be allowed to access the platform administration of OneLab
- The OQ Platform administrator user must have been created or enabled (if user already existed) by an effective platform administrator and credentials must have been communicated to the OQ performer

OQ platform administrator work email:	,	
OQ platform administrator password:		

• OQ Platform administrator user must be disabled by a "real" platform administrator after the OQ Process has been performed

b. Requirements: about configuration variables

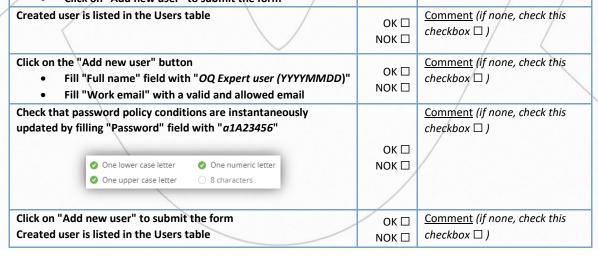
Following settings are set during the IQ Process and should be communicated to the OQ performer so that workflows can be executed properly.

/
locked:





☐ Workflows are based o	n default password policy	☐ Passwo	ord policy ha	as been customized:
One lower case letter	One numeric letter			
One upper case letter	○ 8 characters			
Workflow 1: Platf	orm administratio	n		/
uirements: Platform installed with a	license added			,
ted features:				
Platform administr	ation: user creation			
Platform administr	ation: lab creation			
Platform administr	ation: lab members mana	igement		
 Password policy co. 				
 Audit trail with a re 				
to OneLab URL	43011		/	Comment (if none, check this
in using OQ Platform adm	nistrator credentials		OK □ NOK □	checkbox □)
k on the user's avatar in th k on the Platform administ				$\frac{\text{Comment}}{\text{checkbox}}$ \Box)
	OQ Platform admi		/	
	OQ_Platform_admin@	/	ок □	
≗ Profi	e settings orm administration	_ /	NOK □	
① Log			/	
			/	
tform administration dashl	noard is displayed			
k on "Users" link in the left		/	/	Comment (if none, check this
k on the "Add new user" b				checkbox □)
	with "OQ Lab admin (YYYY		ок □	
■ ✓ Fill "Work amail" fig	ld with a valid and allowed	email/	NOK □	/
/	with "Test_User_1234"	/	NOK 🗖	/





Click on the "Add new user" button • Fill "Full name" field with "OQ Operator (YYYYMMDD)" • Fill "Work email" with a valid and allowed email	ок □	$\frac{\text{Comment (if none, check this }}{\text{checkbox } \square})$
 Fill "Password" field with "Test_User_4321" Click on "Add new user" to submit the form 	NOK □	
Created users are listed in the Users table		$\frac{\text{Comment (if none, check this}}{\text{checkbox }\square})$
Filter by: All V Start light date Onstalla Admini Commercial Network connected to a sengend date Onstalla Admini Commercial Network connected to a sengend date Onstalla Admini Commercial Network connected to a sengend date On College (Commercial Commercial Network connected to a sengend date On College (Commercial Commercial On College (Commercial On College	OK □ NOK □	
Click on "Labs" link in the left menu Click on the "Create new lab" button		Comment (if none, check this checkbox \square)
 Fill "Lab name" field with "OQ Lab (YYYYMMDD)" Fill "Company or division name" field with "Test Company" Click on "Create new lab" to submit the form 	OK □ NOK □	
Created lab is listed in the Labs table	ok □	$\frac{\text{Comment}}{\text{checkbox}} (if none, check this} $
OQ.Lab (20219722) Text Company 11:35 am 11:35 am 1:	NOK □	
Click on the created lab line Check that OQ Platform administrator user is the Lab admin	OK □ NOK □	Comment (if none, check this checkbox □)
Click on the "Add users" button at the bottom of the page In the popup, select " OQ Lab admin (YYYYMMDD)" and submit by clicking on "Add 1 user" button	OK □ NOK □	$\frac{\text{Comment}}{\text{checkbox}}$ (if none, check this checkbox □)
User is added and automatically designated as an expert user		$\frac{\text{Comment}}{\text{checkbox}} \text{ (if none, check this }$
Onclab Addrein Onclab Addrein Onclab Addrein Onclab Addrein Onclab Addrein (00219722) OLabaterro@waren.com	OK □ NOK □	
Check that OQ Platform administrator lab admin's role cannot be changed (buttons cannot be clicked)	OK □ NOK □	Comment (if none, check this checkbox □)
Change " OQ Lab admin (YYYYMMDD)" role to Lab admin	OK □ NOK □	$\frac{Comment}{checkbox}$ $$ <i>j</i>
Check that OQ Platform administrator role can now be changed (buttons can now be clicked)	OK □ NOK □	Comment (if none, check this checkbox □)
Unassign him from the lab by clicking on the cross at the end of the line		Comment (if none, check this checkbox □)
Lab admin Expert user Operator Unassign from this lab	OK □ NOK □	



1.4 Workflow 2: Lab management & permissions

Requirements:		
Workflow 1 has been validated		
Tested features:		
 Lab management: invite a user 		
 Lab management: members role administration 		
An expert user can design a protocol		
An operator cannot design a protocol		
Go to OneLab URL Work email: email entered for user OQ Lab admin (YYYYMMDD) in Workflow 1 Password: "Test_User_1234"	OK □ NOK □	<u>Comment</u> (if none, check this checkbox □)
Check in the top left corner that user is automatically logged in lab "OQ Lab (YYYYMMDD)"	OK □ NOK □	Comment (if none, check this checkbox □)
Click on the lab menu Click on "Manage members" OQ Lab (20210716) TEST COMPANY 1 member Manage members Edit lab settings Edit View lab audit trail ① Create a new lab	OK □ NOK □	Comment (if none, check this checkbox □)

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In the "Work mail" field, enter email used for "OQ Expert user		Comment (if none, check this
(YYYYMMDD)"	OK 🗆	checkbox □)
Check that the role is automatically set to "Expert user" Submit by clicking on "Send invitation"	NOK □	
Click on "Invite new member" button again		Comment (if none, check this
In the "Work mail" field, enter email used for "OQ Operator	ок □	checkbox □)
(YYYYMMDD)"	NOK □	eneekbek 🗀)
Check that the role is automatically set to "Expert user"	NO.C.	
Change the role to "Operator"	ОИП	Comment (if none, check this
Submit by clicking on "Send invitation"	OK □ NOK □	checkbox □)
	NOK 🗆	/
A green feedback is displayed to confirm that the invitation has	ок □	Comment (if none, check this
been sent	NOK □	checkbox □)
Check that members table is automatically displaying the		Comment (if none, check this
"Invites" tab instead of the "Active" tab	ок □	checkbox □)
\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	NOK □	circulation in the circulation i
Check that both invited users are listed		Comment (if none, check this
		checkbox □)
Email address 🕈 Invitation sender Invitation date	ок □	
OQ Lab admin (20210722) ul 22, 2021	NOK 🗆	
Oqoperator@waters.com OQ Lab admin (20210722) Jul 22, 2021	NO.	
)	
Land Could	/	Company to the same about their
Log out from OneLab Log in OneLab with "OQ Expert user" credentials	/	Comment (if none, check this checkbox \square)
Work email: email entered for "OQ Expert user	ок □	CHECKDOX □)
(YYYYMMDD)"	NOK □	
• Password: "a1A23456"	/	
		/
Depending on the lab creation policy:		Comment (if none, check this
	/ /	Comment (if none, check this checkbox □)
Depending on the lab creation policy: If "none": A welcome to OneLab screen is displayed	/ /	
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If "many" or "one":		
Click on the lab menu		
 Click on "OQ Lab (YYYYMMDD)" in the "switch to lab" 		
section		
"-1" OQ Expert user (202 WATERS		
1 member		
Manage members		
± € Edit lab settings		
E _Q , View lab audit trail		
Switch to lab		
OQ Lab (20210722)		
Check in the top left corner that user is now in "OQ Lab"	The second second	
	E YUE WE THE	
(YYYYMMDD)"		/
Check that the "Design protocol" button can be clicked		Comment (if none, check this
		checkbox □)
HOME PROJECTS DEVICES LIBRARY		
	ОК □	
	NOK □	
		/
	/	
Log out from OneLab	/	Comment (if none, check this
Log in OneLab with "OQ Operator" credentials	ок □	checkbox □)
Work email: email entered for "OQ Operator (YYYYMMDD)"	NOK □	
	NOK 🗆	
Password: "Test_User_4321"	/	/
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Depending on the lab creation policy: If "none": A welcome to OneLab screen is displayed A message displays that user does not have access to any labs If "many" or "one": A welcome to OneLab screen is displayed A name must be given to the user's lab and is prefilled with "OQ Expert user (YYYYMMDD)'s Lab" Select one of the applications displayed Click on "Go to OneLab!" button in the top right corner User is directed to the homepage of OQ Operator (YYYYMMDD)'s lab In the bottom left corner, an invitation card from OQ Lab admin to join OQ Lab is displayed	NOK □	checkbox □) Comment (if none, check this
Depending on the lab creation policy: If "none": A welcome to OneLab screen is displayed A message displays that user does not have access to any labs If "many" or "one": A welcome to OneLab screen is displayed A name must be given to the user's lab and is prefilled with "OQ Expert user (YYYYMMDD)'s Lab" Select one of the applications displayed Click on "Go to OneLab!" button in the top right corner User is directed to the homepage of OQ Operator (YYYYMMDD)'s lab In the bottom left corner, an invitation card from OQ Lab admin to join OQ Lab is displayed	NOK □	checkbox □) Comment (if none, check this
Depending on the lab creation policy: If "none": A welcome to OneLab screen is displayed A message displays that user does not have access to any labs If "many" or "one": A welcome to OneLab screen is displayed A name must be given to the user's lab and is prefilled with "OQ Expert user (YYYYMMDD)'s Lab" Select one of the applications displayed Click on "Go to OneLab!" button in the top right corner User is directed to the homepage of OQ Operator (YYYYMMDD)'s lab In the bottom left corner, an invitation card from OQ Lab admin to join OQ Lab is displayed	NOK □	Comment (if none, check this checkbox □)
Depending on the lab creation policy: If "none": A welcome to OneLab screen is displayed A message displays that user does not have access to any labs If "many" or "one": A welcome to OneLab screen is displayed A name must be given to the user's lab and is prefilled with "OQ Expert user (YYYYMMDD)'s Lab" Select one of the applications displayed Click on "Go to OneLab!" button in the top right corner User is directed to the homepage of OQ Operator (YYYYMMDD)'s lab In the bottom left corner, an invitation card from OQ Lab admin to join OQ Lab is displayed	OK NOK	checkbox □) Comment (if none, check this
Depending on the lab creation policy: If "none": A welcome to OneLab screen is displayed A message displays that user does not have access to any labs If "many" or "one": A welcome to OneLab screen is displayed A name must be given to the user's lab and is prefilled with "OQ Expert user (YYYYMMDD)'s Lab" Select one of the applications displayed Click on "Go to OneLab!" button in the top right corner User is directed to the homepage of OQ Operator (YYYYMMDD)'s lab In the bottom left corner, an invitation card from OQ Lab admin to join OQ Lab is displayed	OK O	Comment (if none, check this checkbox □)
Depending on the lab creation policy: If "none": A welcome to OneLab screen is displayed A message displays that user does not have access to any labs If "many" or "one": A welcome to OneLab screen is displayed A name must be given to the user's lab and is prefilled with "OQ Expert user (YYYYMMDD)'s Lab" Select one of the applications displayed Click on "Go to OneLab!" button in the top right corner User is directed to the homepage of OQ Operator (YYYYMMDD)'s lab In the bottom left corner, an invitation card from OQ Lab admin to join OQ Lab is displayed Pending mutation Click on "Accept invitation"	OK NOK	Comment (if none, check this checkbox □) Comment (if none, check this checkbox □)
Depending on the lab creation policy: If "none": A welcome to OneLab screen is displayed A message displays that user does not have access to any labs If "many" or "one": A welcome to OneLab screen is displayed A name must be given to the user's lab and is prefilled with "OQ Expert user (YYYYMMDD)'s Lab" Select one of the applications displayed Click on "Go to OneLab!" button in the top right corner User is directed to the homepage of OQ Operator (YYYYMMDD)'s lab In the bottom left corner, an invitation card from OQ Lab admin to join OQ Lab is displayed Click on "Accept invitation" A green feedback is displayed	OK O	Comment (if none, check this checkbox □) Comment (if none, check this checkbox □)
Depending on the lab creation policy: If "none": A welcome to OneLab screen is displayed A message displays that user does not have access to any labs If "many" or "one": A welcome to OneLab screen is displayed A name must be given to the user's lab and is prefilled with "OQ Expert user (YYYYMMDD)'s Lab" Select one of the applications displayed Click on "Go to OneLab!" button in the top right corner User is directed to the homepage of OQ Operator (YYYYMMDD)'s lab In the bottom left corner, an invitation card from OQ Lab admin to join OQ Lab is displayed Accept invitation Click on "Accept invitation" A green feedback is displayed Depending on the lab creation policy:	OK NOK	Comment (if none, check this checkbox □) Comment (if none, check this checkbox □) Comment (if none, check this checkbox □)
Depending on the lab creation policy: If "none": A welcome to OneLab screen is displayed A message displays that user does not have access to any labs If "many" or "one": A welcome to OneLab screen is displayed A name must be given to the user's lab and is prefilled with "OQ Expert user (YYYYMMDD)'s Lab" Select one of the applications displayed Click on "Go to OneLab!" button in the top right corner User is directed to the homepage of OQ Operator (YYYYMMDD)'s lab In the bottom left corner, an invitation card from OQ Lab admin to join OQ Lab is displayed Accept invitation Click on "Accept invitation" A green feedback is displayed Depending on the lab creation policy: If "none":	OK NOK OK NOK	Comment (if none, check this checkbox □) Comment (if none, check this checkbox □)
Depending on the lab creation policy: If "none": A welcome to OneLab screen is displayed A message displays that user does not have access to any labs If "many" or "one": A welcome to OneLab screen is displayed A name must be given to the user's lab and is prefilled with "OQ Expert user (YYYYMMDD)'s Lab" Select one of the applications displayed Click on "Go to OneLab!" button in the top right corner User is directed to the homepage of OQ Operator (YYYYMMDD)'s lab In the bottom left corner, an invitation card from OQ Lab admin to join OQ Lab is displayed Accept invitation Click on "Accept invitation" A green feedback is displayed Depending on the lab creation policy:	OK NOK	Comment (if none, check this checkbox □) Comment (if none, check this checkbox □) Comment (if none, check this checkbox □)



If "many" or "one":		
Click on the lab menu		
 Click on "OQ Lab (YYYYMMDD)" in the "switch to lab" 		
section		
-† OQ Operator (20210		
WATERS 1 member		
Manage members		
Eq. View lab audit trail		/
Switch to lab		/
OQ Lab (20210722)		
⊙ Create a new lab		/
		/
Check in the top left corner that user is now in "OQ Lab		
(YYYYMMDD)"		/
Check that the "Design protocol" button is disabled		Comment (if none, check this
		checkbox □)
	ок □	
You do not have permission to design a protocol		/
Design protocol Execute experiment	NOK □	
Log out from OneLab	/	Comment (if none, check this
Log out Holli Official	ок □	/
	NOK □	checkbox □)
	/	

1.5. Workflow 3: Design & Execute (SaaS / Minor release OQ Process)

Requirements:

- Full OQ Process: Workflow 2 has been validated
- SaaS / Minor release OQ Process:
 - For each workflow, log in with a user having one of the roles listed in the related requirementsthis could be a user created in an earlier qualification workflow, one of your own configured users, or, when using an outside expert to run qualification, a user account / accounts configured specifically for this individual
 - All used users should be in the same lab

A) Design a protocol

Requirements:			
SaaS / Minor release OQ Process: Log in with a user being a lab admin or an			
	expert user		
Tes	ted features:		
•	Create a project		
•	Import a protocol		
•	Design a protocol		
•	Import reagents from a data table into a labware		
Go	to OneLab URL	01/ 🗆	Comment (if none, check this
•	Work email: email entered for "OQ Expert user (YYYYMMDD)"	OK 🗆	checkbox □)
•	Password: Test_User_1234	NOK □	
Che	ck in the top left corner that user is in "OQ Lab (YYYYMMDD)"	ок □/	Comment (if none, check this
		NOK □	checkbox □)
		None	
	k on "PROJECTS" tab at the top center of the screen	ОК □	Comment (if none, check this
Clic	k on the card "New project"	NOK □	checkbox □)
The	form to create a new project is displayed	NOK 🗆	



Fill "Project name" field with "OQ Project (YYYYMMDD)"		Comment (if none, check this
Let the "Description" field empty	ок □	checkbox □)
Select a project color	NOK □	
Check that "Initials" field is automatically filled with "OQ"	NOK 🗆	
Click on "Create project" button		
A green feedback is displayed to confirm project creation	ок □	Comment (if none, check this
The new created project is automatically opened	NOK □	checkbox □)
The selected color is correct, and initials are OQ		
Click on the link "Import protocol file (.onp)"		Comment (if none, check this
		checkbox □)
Protocols + Design new Import protocol file (.onp)	OK □ NOK □	
Select the dedicated OQ protocol furnished with the OQ process		
A green feedback is displayed to confirm the successful import	ок □	Comment (if none, check this
	NOK □	checkbox □)
The protocol is listed in the project	ок □	Comment (if none, check this
	NOK □	checkbox □)
	IVOR	
Click on the "Design new" button		Comment (if none, check this
	OK [checkbox □)
Protocols 1 + Design new Import protocol file (.onp)	OK 🗆	/
Protocols 1 Seagrica import protocol me (sing)	NOK □	
	/	
The designer opens on a New protocol		Comment (if none, check this
The version of the protocol is V.1		checkbox □)
	Ок □	
	NOK □	
New protocol	NOK	
	/	
An onboarding message asking to "add a labware to the bench" is		Comment (if none, check this
displayed	/ OK □	$\frac{\text{comment}}{\text{checkbox}} \square$
uispiayeu	NOK □	CHECKBOX [1]
Click on the protocol name	/	Comment (if none, check this
Protocol information screen is displayed	OK □	checkbox □)
	NOK □	
Change protocol title to "OQ protocol (YYYYMMDD)"	OK \square	Comment (if none, check this
Click on update button	OK □ NOK □	checkbox □)
	NOK 🗆	
Bench is displayed again	ок □	Comment (if none, check this
Protocol title has been correctly updated	NOK □	checkbox □)
Click the "Import solution at start" icon in the toolbar		Canana ant life a ana abant this
Click the "Import solution at start" icon in the toolbar		Comment (if none, check this checkbox \square)
		checkbox 🗆)
Import solution at start	OK □	
	NOK □	
The dedicated screen is displayed		/
Copy the dedicated sheet "OQ Import Solution (Workflow3)" to	ок □/	Comment (if none, check this
your clipboard (ctrl+c)	NOK □	checkbox □)
Paste from clipboard using the dedicated button	/	Commont lift name shock this
raste nom chippoard using the dedicated putton	OK □	Comment (if none, check this checkbox \square)
	NOK □	CHECKBOX LI)



Paste from clipboard		
A warning message is displayed "A well cannot contain more than one solution"		Comment (if none, check this checkbox □)
A well cannot contain more than one solution • Multiple solutions found in the same well A1 (line 1, 2) Please select the one you want to use in this well	OK □ NOK □	
Click the first checkbox for A1 position Check that related warning message is no more displayed	OK □ NOK □	$\frac{\text{Comment}}{\text{checkbox}} (\text{if none, check this} \\ \text{checkbox} \square)$
Click the "Select your labware" button	OK □ NOK □	$\frac{\text{Comment}}{\text{checkbox}} \text{ (if none, check this }$
Check that only 384 microplates can be selected in the catalog (filter should be automatically applied on 384 number of wells)	OK □ NOK □	Comment (if none, check this checkbox □)
Select "Greiner, 384-well standard microplate" by clicking on the dedicated button	OK □	Comment (if none, check this checkbox □)
Click on "Create and fill labware" button Bench with the microplate is displayed again, filled with solutions previously imported		Comment (if none, check this checkbox □)
Greiner, 384-well standard microplate	OK □ NOK □	
Click on the "Add labware" icon in the toolbar	OK □ NOK □	Comment (if none, check this checkbox □)
In the well capacity filter, click on "50 mL - 250 mL"	OK □ NOK □	Comment (if none, check this checkbox □)
Check that only related labware are displayed	OK □ NOK □	Comment (if none, check this checkbox □)
Select "Falcon 50mL conical centrifuge tube" by clicking the "Add" button	OK □ NOK □	Comment (if none, check this checkbox □)



Falcon® 50 mL conical centrifuge tube		
Click the "Add to bench" button	OK □ NOK □	$\frac{\text{Comment}}{\text{checkbox}} (\text{if none, check this} \\ \text{checkbox} \square)$
Back on the bench, click on the microplate and drag the cursor to the 50mL tube	OK □ NOK □	$\frac{\text{Comment}}{\text{checkbox}} \text{ (if none, check this }$
On the screen dedicated to select sources, click on A1 and B1 Click on Save selection	OK □ NOK □	Comment (if none, check this checkbox □)
In the volume field, enter 10 and check that the button to "Save" the step turns from disabled to enabled Click on Save step	OK □ NOK □	Comment (if none, check this checkbox □)
Back to the bench, the created step is listed, and an arrow is displayed from the microplate to the tube	OK □ NOK □	$\frac{\text{Comment}}{\text{checkbox}} (\text{if none, check this} \\ \text{checkbox} \square)$
Click on the tube In the labware menu, click on the three dots then on "Define as target of the protocol"		Comment (if none, check this checkbox □)
Rename Replicate Delete Replace latiware View latiware info Policin® 50 mL conical commit Uniter Tall in with a sample reference at start Import solution at start Define as target of the protocol	OK □ NOK □	
On the bench, the tube should have a "Target" label	OK □ NOK □	Comment (if none, check this checkbox □)
Click on the "Actions" icon in the toolbar Actions Actions to apply on labware	OK □	Comment (if none, check this checkbox □)
Click the Heat/cool action icon	OK □ NOK □	Comment (if none, check this checkbox □)
Click on the microplate and drag it to the dedicated zone "Labware to heat"	OK □ NOK □	Comment (if none, check this checkbox □)



- Labware to heat		
Greiner, 384-well		
standard microplate 😠		
AUTO (7 μL)	No.	100 100 100 100 100 100 100
ψ		
Drag and drop the labware to heat here		
Select the temperature of 37 °C		Comment (if none, check this
Select the temperature of 37°C	ок □	checkbox \square)
	NOK □	CHECKBOX []
Check that the advanced option to place the labware only once the		Comment (if none, check this
device reached the desired temperature is checked		checkbox □)
device reached the desired temperature is checked		CHECKBOX []
		/
Advanced	ок □	
Labware must be placed in the device once it reaches the desired	NOK □	/
temperature		
Labware must be removed from the heat/cool device after protocol step		
		. /
Check that the advanced option to remove the labware from the	ок□	Comment (if none, check this
device once the protocol has been done is checked	NOK □	checkbox □)
	110/. =	
Save the step	ок □	Comment (if none, check this
Back to the bench, the "Heat/cool" icon should be displayed above	NOK □	checkbox □)
the microplate and should be orange	/ NOK =	
Above the steps list, click the Reorder button	/////	Comment (if none, check this
	/ /	checkbox □)
	/	CHECKBOX 🗆)
STEPS LABWARE INFO		CHECKBOX 🗆)
	ок□	CHECKBOX []
STEPS LABWARE INFO Reorder	OK □ NOK □	CHECKBOX []
	/	CHECKBOX []
Reorder	/	CHECKBOX []
Reorder ① 0. Start	NOK □	
Drag the Start heating step from position 2 to position 1, so that the	NOK □	Comment (if none, check this
Reorder ① 0. Start	NOK □	
Drag the Start heating step from position 2 to position 1, so that the	NOK □	Comment (if none, check this
Drag the Start heating step from position 2 to position 1, so that the pipetting gets in between the start and the stop	NOK □	Comment (if none, check this
Drag the Start heating step from position 2 to position 1, so that the	NOK □	Comment (if none, check this
Drag the Start heating step from position 2 to position 1, so that the pipetting gets in between the start and the stop O. Start	NOK □	Comment (if none, check this
Drag the Start heating step from position 2 to position 1, so that the pipetting gets in between the start and the stop O. Start O.	NOK □	Comment (if none, check this
Drag the Start heating step from position 2 to position 1, so that the pipetting gets in between the start and the stop O. Start O. S	NOK □	Comment (if none, check this
Drag the Start heating step from position 2 to position 1, so that the pipetting gets in between the start and the stop O. Start O. Start O. Start O. Start O. Start O. O. Start O	NOK □	Comment (if none, check this
Drag the Start heating step from position 2 to position 1, so that the pipetting gets in between the start and the stop O. Start O.	NOK □	Comment (if none, check this
Drag the Start heating step from position 2 to position 1, so that the pipetting gets in between the start and the stop	NOK □	Comment (if none, check this
Drag the Start heating step from position 2 to position 1, so that the pipetting gets in between the start and the stop O. Start O. S	NOK □	Comment (if none, check this
Drag the Start heating step from position 2 to position 1, so that the pipetting gets in between the start and the stop O. Start 1. Start heating Greiner, 384- well standard microplate at 37 °C for 1 minutes 2. Dispense 10 µL from Greiner, 384-well standard microplate A1 to Falcon® 50 mL conical centrifuge tube 3. Stop heating Greiner, 384- ‡	NOK □	Comment (if none, check this
Drag the Start heating step from position 2 to position 1, so that the pipetting gets in between the start and the stop • 0. Start • 0	NOK □	Comment (if none, check this
Drag the Start heating step from position 2 to position 1, so that the pipetting gets in between the start and the stop O. Start 1. Start heating Greiner, 384-well standard microplate at 37 of for 1 minutes 2. Dispense 10 µL from Greiner, 384-well standard microplate A1 to Falcon® 50 mL conical centrifuge tube 3. Stop heating Greiner, 384-well standard microplate at 37	NOK □	Comment (if none, check this
Drag the Start heating step from position 2 to position 1, so that the pipetting gets in between the start and the stop O. Start 1. Start heating Greiner, 384- well standard microplate at 37 °C for 1 minutes 2. Dispense 10 µL from Greiner, 384-well standard microplate A1 to Falcon® 50 mL conical centrifuge tube 3. Stop heating Greiner, 384- well standard microplate at 37 °C after 1 minutes	NOK □	Comment (if none, check this
Drag the Start heating step from position 2 to position 1, so that the pipetting gets in between the start and the stop • 0. Start • 0	NOK □	Comment (if none, check this
Drag the Start heating step from position 2 to position 1, so that the pipetting gets in between the start and the stop	NOK □	Comment (if none, check this
Drag the Start heating step from position 2 to position 1, so that the pipetting gets in between the start and the stop O. Start O. S	NOK NOK	Comment (if none, check this checkbox □)
Drag the Start heating step from position 2 to position 1, so that the pipetting gets in between the start and the stop	NOK □	Comment (if none, check this

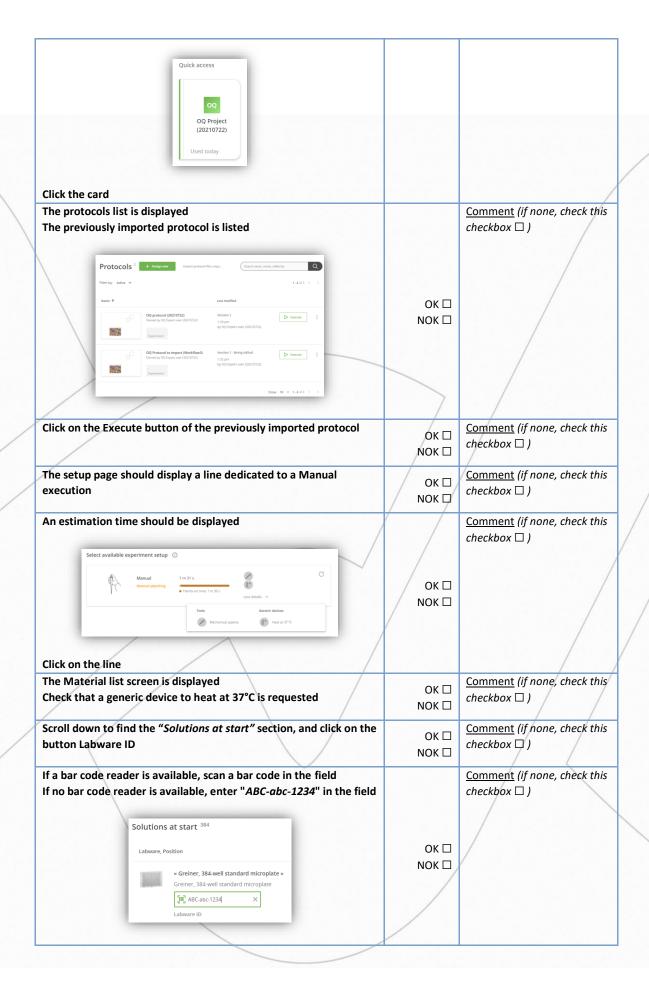


Click the winettine stee /n	-:+: 2\			Commont life and about this
Click the pipetting step (po			ок □	Comment (if none, check this checkbox \square)
In the labware menu, chec		olaved	NOK □	CHECKBOX 11
Click on "2 solutions"		,		Comment (if none, check this
Check that A1 well is flagge	ed as a sample			checkbox □)
Check that B1 is not flagge	d as a sample			
Total volum	e		OV E	
20 μL	STEP 2		OK 🗆	
No solution	at start yet 🛕		NOK □	
• Sample	a A1 0.5 a.u.			
• B1	0.5 pg/nL			
Click on the "Execute butto	on"			Comment (if none, check this
			OK 🗆	checkbox □)
			NOK □	
The setup page should disp	olay a line dedicated to a I	Manual	ок □	Comment (if none, check this
execution			NOK □	checkbox □)
An estimation time should			NO.K.	/
Click on cancel and check t	hat the designer is display	ed again	ок □	Comment (if none, check this
			NOK □	checkbox □)
Click the OneLab icon to ex	it the designer			Comment (if none, check this
			/	checkbox □)
			/ ок □	
OQ protocol (202107:	22) 存 V.1 🔒 🗍 🗎	> Execute	NOK □	
Go back to OneLab			/	
The protocols list of "OQ P	<i>roject (YYYYMMDD)</i> " is di	isplayed /	ок□	Comment (if none, check this
		/	NOK □	checkbox □)
Log out from OneLab		V	/	Comment (if none, check this
			OK □	checkbox □)
			NOK L	

B) Execute a protocol

Rec •	uirements: SaaS / Minor release OQ Process: Log in with a user being an ope	erator, or an	
	expert user or a lab admin		
Tes	ted features:		
•	Execute a protocol: bar code scanning for labware & sample	r'S	
•	Execute a protocol: manual execution		
•	Experiment report: electronic signature		
•	Experiment report: release & sign a report		
Log •	in OneLab with "OQ Operator" credentials Work email: email entered for "OQ Operator (YYYYMMDD)" Password: "Test_User_4321"	OK □ NOK □	$\frac{\text{Comment}}{\text{checkbox}}$ (if none, check this checkbox \square)
	"OQ Project (YYYYMMDD)" card is displayed in the Quick ess area	OK □ NOK □	$\frac{\text{Comment}}{\text{checkbox}} \text{ (if none, check this }$







Check that a Sample ID button is available for all wells on the A		Comment (if none, check this
line and enter "Sample_A1" in A1 field		checkbox □)
A1 • Sample A1	ок □	
[IIII] Sample_A1	NOK □	
	NOK 🗀	
Sample ID		
A1 sample desc.		
		/
Check that no "sample ID" button is available for all wells on the B	ок □	Comment (if none, check this
line	NOK □	checkbox □)
	NOK 🗆	
Scroll down to find the "Other materials" section, and click on the		Comment (if none, check this
button Labware ID of the targeted tube		checkbox □)
Enter "Targeted tube" in the field		
Other materials 1	ок □	
	NOK □	
Labeare Label to write		
Falcon® 50 mL conical centrifuge tube tentrifuge tube tentrifuge tube falcon® 50 mL conical centrifuge tube tube tube		
Labware ID		/
Scroll up to the top of the material list and click the Start	OK/	Comment (if none, check this
experiment button	OK □	checkbox □)
	NOK □	
First step of the execution asks to check that the heating device is	/	Comment (if none, check this
at 37°C	/ OK □	checkbox □)
Click on the next step button	NOK □	eneckbox =)
A start button is available to start the timer	/ /	Commant (if name shock this
	ОК □	Comment (if none, check this
Click on the start button	NOK □	checkbox □)
The beaution through displayed as a dedicated and in the	/	
The heating timer is displayed on a dedicated card, in the	/	Comment (if none, check this
"simultaneous activity" section of the runner	/	checkbox □)
	/	/
Simultaneous activity	OK □	
Greiner, 384-well stan	NOK □	
§+ 00:55		
8 00:55		
During the heating, the pipetting step from A1, B1 to the tube is		Comment (if none, check this
displayed	ок □	checkbox \square)
A sample tag is displayed under the microplate		CHECKBOX 11
Click on the continue button	NOK □	
Wait until the "end of heating" step is displayed		Comment (if none, check this
Once timer is finished, continue button switches from disabled to	ок □	checkbox □)
enabled	NOK □	
Click on the continue button		
Last step asks the user to remove the microplate from the device	ок □	Comment (if none, check this
Click on "End experiment" button		checkbox □)
	NOK □	
Experiment report is displayed	6	Comment (if none, check this
	OK 🗆	checkbox □)
	NOK □	
Scroll down to the Target labware section	/	Comment (if none, check this
Check that Labware ID is "Targeted tube"	OK □	checkbox \square)
Check that Sample ID is "Sample_A1"	NOK □	CHECKBON LI /
check that sample to is sumple_A1		



Click the "Autofill all of child IDs" button Check that Sample_A1 child ID is automatically filled, and its value is "Sample_A1_1" [iii] Sample_A1_1 × Child ID	OK □ NOK □	Comment (if none, check this checkbox □)
Check that the "Export sample information" button is not available Check that the "Print" button at the top of the screen is not available	OK □ NOK □	$\frac{\text{Comment}}{\text{checkbox}} \left(\text{if none, check this} \right)$
Click the "Release report" button at the top of the screen In the reason field, enter "To test Report releasing" In the credential fields, enter: Work email: email entered for "OQ Operator (YYYYMMDD)" Password: Test_User_4321 Click the "Sign experiment report" button	OK □ NOK □	Comment (if none, check this checkbox □)
Check that the report is correctly released and signed by "OQ Operator (YYYYMMDD)" Released and signed by OQ Operator (20210722) Oqoperator@waters.com Jul 22, 2021 at 1:55:23 PM « To test Report releasing »	OK □ NOK □	Comment (if none, check this checkbox [])
Check that the Print button at the top of the screen is now available Check that the Export sample information is now available Click on "Go to OneLab home"	OK □ NOK □	Comment (if none, check this checkbox □)
Log out from OneLab	OK □ NOK □	Comment (if none, check this checkbox □)

C) Review and archive a protocol

Requirements: • SaaS / Minor release OQ Process: Log in with a user being a lab a	dmin	
Tested features:		
Experiment report: review a report		
Archive a protocol		
Log in OneLab with "OQ Lab admin" credentials Work email: email entered for "OQ Lab admin (YYYYMMDD)" Password: "Test_User_1234"	OK □ NOK □	$\frac{\text{Comment}}{\text{checkbox}} (\text{if none, check this } \\ \text{checkbox} \square)$
On the homepage, click the "All lab activity" link My recent activity All lab activity	OK □ NOK □	Comment (if none, check this checkbox □)
A line dedicated to the previous experiment report release is displayed	OK □ NOK □	Comment (if none, check this checkbox □)



Today OQ Operator (20210722) released and signed the experiment report OQ Protocol to import (Workflow3) Click on the experiment report link on this line		
The experiment report is displayed, and a "review" button is available		Comment (if none, check this checkbox $□$)
CQ Protocol to import (Workflow3) : + co Lab (2019722) Experiment completed	OK □ NOK □	
Click the "Review" button at the top of the screen In the reason field, enter "To test Report reviewing" In the credential fields, enter: Work email: email entered for "OQ Lab admin (YYYYMMDD)" Password: Test_User_1234 Click the "Review experiment report" button	OK □ NOK □	<u>Comment</u> (if none, check this checkbox □)
Check that the report is correctly reviewed by "OQ Lab admin		Comment (if none, check this
(YYYYMMDD)" Reviewed by OQ Lab admin (20210722) OQLabadmin@waters.com	OK 🗆	checkbox □)
Jul 22, 2021 at 2:05:57 PM « To test Report reviewing » Click on the Protocols link on the left of the screen		Comment (if none, check this
Protocols	ок□	checkbox □)
② Experiments	NOK □	
The protocols list is displayed The previously imported protocol is listed		Comment (if none, check this checkbox □)
OD protocol (20210722) Owned by OD Expert user (20210722) Experiment OD Protocol to import (Warkflow3) Oned by OD Expert user (20210722) 1 133 pm by OD Expert user (20210722) 1 133 pm by OD Expert user (20210722)	OK □ NOK □	
In the protocols list, click on the three dots at the end of the line related to the protocol "OQ Protocol to import (Workflow3)"	OK □ NOK □	Comment (if none, check this checkbox □)
Click the Archive button	OK □ NOK □	Comment (if none, check this checkbox □)



In the dedicated pop up, enter the reason "To t <i>est protocol</i> archiving"	OK □ NOK □	$\frac{Comment}{checkbox}$ ☐ $\frac{1}{2}$
Check that the protocol is no longer listed in the protocols list, under the "filter by: Active" which is selected by default	OK □ NOK □	Comment (if none, check this checkbox □)
Change the filter value to select "Archived" and check that "OQ Protocol to import (Workflow3)" is listed with an archived tag and that it cannot be executed anymore		$\frac{\text{Comment}}{\text{checkbox}}$ \Box)
OO Protocol to import (Workflow3) Owned by OQ Expert user (00210722) 1	OK □ NOK □	
Click the lab menu in the top left corner	OK □ NOK □	$\frac{\text{Comment}}{\text{checkbox}} \left(\text{if none, check this} \right)$
Click the " View lab audit trail entry	OK □ NOK □	$\frac{\text{Comment}}{\text{checkbox}} (\text{if none, check this} \\ \text{checkbox} \square)$
A line related to the previous experiment report review must be displayed	OK □ NOK □	$\frac{\text{Comment}}{\text{checkbox}} (\text{if none, check this} \\ \text{checkbox} \square)$
A line related to the previous protocol archived must be displayed Click on the line	OK □ NOK □	$\frac{\text{Comment (if none, check this}}{\text{checkbox } \square})$
Check that the reason entered before is correctly displayed	/	$\frac{\text{Comment}}{\text{checkbox}}$ (if none, check this
OQ Lab admin (20210722) (User ID: Gedwq6RJ) archived protocol jul 22, 2021, 2:08.62 PM Protocol "OQ Protocol to Import (Workflow3)" In project "OQ Project (20210722)" Reason: To test protocol archiving	OK □ NOK □	
Log out from OneLab	OK □ NOK □	Comment (if none, check this checkbox □)

1.6. Workflow 4 (optional): Signup & email

Requirements:		
Signup is activated (cf. Installation guide)		
 Emails are activated, either via smtp or logs (cf. Installation gu 	ide)	
Tested features:		
Create an account		
• Emails		
Go to OneLab URL	OK □ NOK □	Comment (if none, check this checkbox \square)
Click on the link "Create a free account" Log in Need a OneLab account? Create a free account	OK □ NOK □	Comment (if none, check this checkbox □)



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Fill "Full name" field with "OQ New User (YYYYMMDD)" Fill "Work email" field with a valid and allowed email Fill "Password" field with "Test_User_0" Click the continue button	OK □ NOK □	Comment (if none, check this checkbox □)		
A screen asking to check your email is displayed Please, check your email We've sent you a message to QQ3@waters.com. Open it and click on * Activate account *.	OK □ NOK □	Comment (if none, check this checkbox □)		
Check that the email has correctly been received	OK □ NOK □	$\underline{\text{Comment}}$ (if none, check this checkbox \Box)		
In the email, click the link to activate the account	OK □ NOK □	Comment (if none, check this checkbox \square)		
The login page of OneLab opens	OK □ NOK □	Comment (if none, check this checkbox \square)		
The work email field is automatically filled with the email entered during the account creation	OK □ NOK □	Comment (if none, check this checkbox □)		
Fill the "Password" field with "Test_User_0" Click on the Login button	OK □ NOK □	Comment (if none, check this checkbox □)		
Depending on the lab creation policy: If "none": A welcome to OneLab screen is displayed A message displays that user does not have access to any labs If "many" or "one": A welcome to OneLab screen is displayed A name must be given to the user's lab and is prefilled with "OQ new User (YYYYMMDD)'s Lab" Select one of the applications displayed Click on "Go to OneLab!" button in the top right corner User is directed on the homepage of OQ New User (YYYYMMDD)'s lab	OK □ NOK □	Comment (if none, check this checkbox □)		

1.7. Workflow 5: Reset

Requirements:	
 This workflow is dedicated to purge the data that have been created during this OQ process. Therefore, it should be used applied to all records created during the OQ execution. 	
Tested features:	
Platform administration: archive a lab	
Platform administration: disable a user	
Go to OneLab URL Log in using OQ Platform administrator credentials OK NOK	$\frac{\text{Comment}}{\text{checkbox}} \text{ (if none, check this }$



Click on the user's avatar in the top right corner Click on the Platform administration link Platform administration dashboard is displayed	OK □	Comment (if none, check this checkbox □)
Click on " <i>Labs</i> " link in the left menu	OK □ NOK □	Comment (if none, check this checkbox □)
Use the search field to filter results on YYYYMMDD All labs created during this OQ process should be listed	OK □ NOK □	$\frac{\text{Comment}}{\text{checkbox}} \text{ (if none, check this }$
Click the select all checkbox An archive button is displayed		Comment (if none, check this checkbox □)
3 labs selected Archive ✓ Name ↓ ✓ OQ Operator (20210722)'s Lab 1 member - No devices ✓ OQ Lab (20210722) 3 members - No devices	OK □ NOK □	
OQ Expert user (20210722)'s Lab 1 member + No devices		
Click the archive button A confirmation pop up is displayed and a reason must be entered to unassign the user from the lab	OK □ NOK □	Comment (if none, check this checkbox □)
Enter a "To test lab archiving" and submit	OK □	Comment (if none, check this checkbox □)
A green feedback indicates that the lab is now archived ② 3 labs have been successfully archived.	OK □ NOK □	Comment (if none, check this checkbox □)
Check that the labs are tagged as archived Filter by: All Name ↑ OQ Expert user (20210722 Archived 1 member • No devices OQ Lab (20210722) Archived 3 members • No devices OQ Operator (20210722 Archived 1 member • No devices	OK □ NOK □	Comment (if none, check this checkbox □)
Click on "users" link in the left menu	OK □ NOK □	Comment (if none, check this checkbox □)
Check all the checkboxes for all users created during this OQ process: OQ Lab admin (YYYYMMDD) OQ Expert user (YYYYMMDD)	OK 🗆	Comment (if none, check this checkbox □)



 OQ Operator (YYYYMMDD) OQ New User (YYYYMMDD) [if workflow 4 was done] 		
Click the "Disable" button		$\frac{\text{Comment}}{\text{checkbox}} (\text{if none, check this} \\$
3 users selected Disable :		
OneLab Admin Platform admin onelab@andrewalliance.com		,
OQ Expert user (20210722) OQExpertuser@waters.com	ок □	
OQ Lab admin (20210722) OQ Labadmin @waters.com	NOK □	
OQ Operator (20210722) Oqoperator@waters.com		
OQ_Platform_admin@waters.com Platform_admin		
A confirmation pop up is displayed and a reason must be entered to unassign the user from the lab		
Enter "To test users deactivation" and submit		Comment (if none, check this
	ок □	checkbox □)
	NOK □	
A green feedback indicates that the users are now disabled		Comment (if none, check this checkbox \square)
This users have been successfully disabled	OK □ NOK □	
Account status for these users is "Disabled"	/	
Quit the platform administration by clicking on the arrow on the		Comment (if none, check this
top left of the screen	ок □	checkbox □)
top left of the screen	NOK □	CIRCUMDOX LL /
	/	
A message indicates that user does not have access to any labs		$\frac{Comment}{(if none, check this)}$ checkbox $□$)
You do not have access to any labs You can ask a colleague or your OneLab administrator for access or to create a new lab. Create a Lab	OK □ NOK □	
Click on the user's avatar in the top right corner		Comment (if none, check this
Log out from OneLab	OK □ NOK □	checkbox □)
On login screen, try to log in with the email and password that		Comment (if none, check this
were set for "OQ Lab admin (YYYYMMDD)"		checkbox □)
An error message indicates that account has been disabled		
	ок □	
Account disabled	NOK □	
Your account has been disabled. If you have any questions, please contact us.		



1.8.0Q test report

Below Operation Qualification Report is shown. The Operation Qualification is successful if all executed workflows passed **ALL** the tests.

	OPERATION QUA	LIFICATION REPORT
OQ test	RESULT	COMMENT (if none, bar the cell)
WORKFLOW 1	OK □ NOK □	
WORKFLOW 2	OK □ NOK □	
WORKFLOW 3	OK □ NOK □	
WORKFLOW 4	OK □ NOK □ NOT APPLICABLE □	
WORKFLOW 5	OK □ NOK □	
Reminder		nents: Itor user must be disabled by an effective platform OQ Process has been performed OK NOK NOK

	Function	Name	Date	Signature
Performed by				
Approved by				

2. Contact

For any questions or information, do not hesitate to:

- Visit our website www.andrewalliance.com
- Contact us through our Intercom messenger.
- Send us an email to aa_support@waters.com
- Visit us:
 - Andrew Alliance S.A. (Headquarters)
 Chemin Grenet 21
 1214 Vernier (Genève), Switzerland

Document generated by Andrew Alliance S.A.

